EMERGENCY USE AUTHORIZATION (EUA) SUMMARY

Labcorp Seasonal Respiratory Virus RT-PCR Test
for use with
Labcorp COVID-19+Flu+RSV Test Home Collection Kit

Laboratory Corporation of America

For In vitro Diagnostic Use
For use under Emergency Use Authorization (EUA) only
For prescription use only
For use with anterior nasal swabs collected from individuals ages 18 years and older (self-collected), 14 years and older (self-collected with adult supervision), or 2 years and older (collected with adult assistance)

(The Labcorp Seasonal Respiratory Virus RT-PCR Test will be performed at the Center for Esoteric Testing in Burlington, North Carolina, or other laboratories designated by Labcorp that are also certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet the requirements to perform high complexity tests, as described in the laboratory procedures that were reviewed by the FDA under this EUA.)

INTENDED USE

The Labcorp Seasonal Respiratory Virus RT-PCR Test is a multiplex real-time reverse transcription (RT) polymerase chain reaction (PCR) test intended for the simultaneous qualitative detection and differentiation of RNA from SARS-CoV-2, Influenza A virus (Flu A), Influenza B virus (Flu B), and/or Respiratory Syncytial Virus (RSV) in nasopharyngeal (NP), mid-turbinate, and anterior nasal swab specimens from individuals suspected of respiratory viral infection consistent with COVID-19 by a healthcare provider. Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2, influenza, or RSV can be similar.

This test is also for use with individual anterior nasal swab specimens that are collected at home using the Labcorp COVID-19+Flu+RSV Test Home Collection Kit from individuals age 18 years and older (self-collected), 14 years and older (self-collected under adult supervision), or 2 years and older (collected with adult assistance) when directly ordered by an HCP. Specimens collected using the Labcorp COVID-19+Flu+RSV Test Home Collection Kit can be transported at ambient temperature for testing.

Testing is limited to the Center for Esoteric Testing, Burlington, NC, or other laboratories designated by Labcorp that are also certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet the requirements to perform high complexity tests.

Results are for the identification and differentiation of RNA from SARS-CoV-2, Influenza A, Influenza B, and RSV. The Labcorp Seasonal Respiratory Virus RT-PCR Test is not intended to detect Influenza C. RNA from Influenza A, Influenza B, RSV, and SARS-CoV-2 is generally detectable in respiratory specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-

CoV-2, influenza A, influenza B, and/or RSV RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other pathogens not detected by the test. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all SARS-CoV-2 results to the appropriate public health authorities.

Negative results do not preclude SARS-CoV-2, Influenza A, Influenza B, and/or RSV infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

The Labcorp Seasonal Respiratory Virus RT-PCR Test is intended for use by qualified laboratory personnel specifically instructed and trained in the techniques of real-time PCR and in vitro diagnostic procedures. The Labcorp Seasonal Respiratory Virus RT-PCR Test is intended for use only under the Food and Drug Administration's Emergency Use Authorization.

DEVICE DESCRIPTION AND TEST PRINCIPLE

1) The Labcorp Seasonal Respiratory Virus RT-PCR Test

The Labcorp Seasonal Respiratory Virus RT-PCR Test is a multiplex real-time reverse transcription polymerase chain reaction (rRT-PCR) test. The test primer and probe sets are designed to detect the nucleocapsid gene of SARS-CoV-2, matrix 1 gene of Influenza A, nonstructural 2 gene of Influenza B, and matrix gene of RSV in nasopharyngeal (NP), mid-turbinate and anterior nasal specimens collected from individuals suspected of respiratory viral infection consistent with COVID-19 by a healthcare provider.
The Labcorp COVID-19+Flu+RSV Test Home Collection Kit will be used for collection of anterior nasal swab specimens at home by patients suspected of respiratory viral infection consistent with COVID-19 by their healthcare provider and for testing with the Labcorp Seasonal Respiratory Virus RT-PCR Test at the Center for Esoteric Testing, Burlington, NC, or other laboratories designated by Labcorp.

2) The Labcorp COVID-19+Flu+RSV Test Home Collection Kit

a) Product Overview:

The Labcorp COVID-19+Flu+RSV Test Home Collection Kit is composed of a shipping box, pre-labeled return envelope, instructions for use, specimen collection materials (nasal swab and saline tube), a specimen biohazard bag and specimen confirmation form.

Table 1: Content of the Labcorp COVID-19+Flu+RSV Test Home Collection Kit

Reagent	**Manufacturer**	**Catalog #**
Shipping box	Therapak	23586G
Instructions	The Dot	Not Applicable
Return envelope	FedEx	163034
Specimen biohazard bag	Therapak	16019G
Nasal foam swab	Super Brush	59-1187-BULK
Saline and tube	Sarstedt	51.550.123

Specimen Confirmation form	The Dot	Not Applicable

b) Home Collection Kit Ordering and Distribution:

The Labcorp COVID-19 + Flu + RSV Test Home Collection Kit is dispensed to patients when prescribed by their physician using the Labcorp provider interface to order diagnostic tests. The kit is intended for use by individuals to collect anterior nasal swab specimens at home, when determined to be appropriate by a healthcare provider (HCP), to aid in the diagnosis of SARS-CoV-2, Influenza A virus (Flu A), Influenza B virus (Flu B), and/or Respiratory Syncytial Virus (RSV) infection. Once the physician order is placed, Labcorp will mail the home collection kit to the patient, who will perform the specimen collection at home and mail the specimen back to Labcorp for testing.

c) Home Collection Kit Use:

The specimen collection and shipping instructions are included in the kit to direct users on how to collect an anterior nasal swab specimen appropriately, place it in the saline transport tube, properly package the specimen and mail it back to the laboratory using the pre-labeled FedEx return envelope. Specimens should be returned on the same day as they were collected.

d) Laboratory Processing (Specimen Accessioning):

When specimens collected using the Labcorp COVID-19 + Flu + RSV Test Home Collection Kit arrive at the testing laboratory they will be accessioned as per the laboratory's SOP. The specimens will be rejected for testing if they meet one or more of the following criteria:

- No saline collection tube included
- No swab included within saline collection tube
- No registration code attached to the saline collection tube
- Saline collection tube leaked resulting in no specimen for testing
- Accession date is greater than 2.5 calendar days (56 hours) from the specimen collection date. Specimens will be rejected if not tested within 3 days after accessioning date under ambient storage conditions.

e) Results Reporting:

For specimens collected with the Labcorp COVID-19 + Flu Test Home Collection Kit, Labcorp will report test results back to the ordering physician and to the patient via the Labcorp patient portal. Upon receiving the result, the physician will follow up on all positive, negative and invalid results by contacting the individuals.

EQUIPMENT AND REAGENTS USED WITH THE LABCORP SEASONAL RESPIRATORY VIRUS RT-PCR TEST

1) Instruments Used with Test

The Labcorp Seasonal Respiratory Virus RT-PCR Test uses the ThermoFisher Scientific KingFisher Flex Magnetic Particle processor for semi-automated specimen extraction. RT-PCR plates are set-up using the Hamilton Microlab STAR liquid handling system and amplification/detection is performed with the Applied Biosystems QuantStudio7 Flex (QS7) using software version 1.3.

2) Description of Test Steps

Nucleic acids are isolated and purified from 200µL of nasopharyngeal (NP), mid-turbinate or anterior nasal specimen using the Thermo Fisher MAGMAX Viral/Pathogen Extraction Kit (MVPII) (Catalog # A48383) and the Thermo Fisher Scientific KingFisher Flex Magnetic Particle processor. Specimens are eluted in a 50µL volume. RT-PCR plates are set-up using the Hamilton Microlab STAR liquid handling system by combining 5µL of the purified, extracted nucleic acids with 15 µL of RT-PCR Master mix.

Specimens are placed on the QS7 instrument for reverse transcription, amplification and detection. In the RT-PCR process, the probe anneals to a specific target sequence located between the forward and reverse primers. During the extension phase of the PCR cycle, the 5' nuclease activity of Taq polymerase degrades the probe, causing the reporter dye to separate from the quencher dye, generating a fluorescent signal. With each cycle, additional reporter dye molecules are cleaved from their respective probes, increasing the fluorescence intensity. Fluorescence intensity is monitored at each PCR cycle by the QS7 instrument.

CONTROLS TO BE USED WITH THE LABCORP SEASONAL RESPIRATORY VIRUS RT-PCR TEST

The Labcorp Seasonal Respiratory Virus RT-PCR Test has the following controls that are run with each extracted set of 93 specimens:

- **No Template Control (NTC):** A negative control consisting of molecular grade nuclease free water is used to detect contamination during extraction and RT-PCR. The NTC should test negative for all targets in the assay, including the RNase P internal control.

- **Negative Extraction Control (NEC)**: A previously characterized negative patient specimen. It serves as a negative control to monitor for any cross-contamination that may occur during the testing procedure.

- **Positive Control (PC)**: A positive template control is used to verify functionality of PCR reagents and that the assay run is performing as intended. The positive control consists of DNA gBlocks (synthesized plasmid-based double-stranded DNA) purchased from Integrated DNA Technologies. Each target sequence (Influenza A, Influenza B, RSV and SARS-CoV-2) is included on a separate gBlock and contains viral genomic sequences encompassing the primer/probe binding regions. The four control gBlocks are added together to form a multiplex control. 150 copies of the Influenza A, Influenza B, and SARS-CoV-2 gBlock and 625 copies of the RSV gBlock are added to each positive control reaction. This equates to approximately 5x the LoD for Influenza A, Influenza B, and SARS-CoV-2 and RSV. The positive control should test positive for all 4 viral targets.

- **Internal control (IC)**: An additional primer/probe set with a distinct flurophore (Cy5) is included in the primer/probe mix that targets human RNase P, which is present in human specimens. This IC is used for every specimen processed and is needed to verify that nucleic acid of adequate quality and quantity is present. This also serves as the extraction and reverse

transcription control to ensure that specimens resulting as negative for test targets contain nucleic acid for testing and that viral RNA has been successfully transcribed into DNA.

INTERPRETATION OF RESULTS

All test controls should be examined prior to interpretation of patient results. Only if a test run is valid, can the results for individual patient specimens be interpreted and reported. Assay targets will be reported as detected (+) if they produce a Ct of ≤ 40 or not detected (-) if they produce a Ct of > 40. Tests negative for all targets are only valid if the RNase P internal control is < 40. Any test resulting as invalid is repeated once. Potential results and corresponding result interpretation are listed in the tables below.

Table 2: The Labcorp Seasonal Respiratory Virus RT-PCR Test Control Results Interpretation

Control	Influenza A Ct Value	Influenza B Ct Value	RSV Ct Value	SARS-CoV-2 Ct Value	RNase P Ct Value
NTC	> 40*	> 40	> 40	> 40	> 40
NEC	> 40	> 40	> 40	> 40	≤ 40
Positive Control	≤ 40	≤ 40	≤ 40	≤ 40	> 40

* an "undetermined" result is the same as "no signal" or a Ct > 40

Table 3: The Labcorp Seasonal Respiratory Virus RT-PCR Test Interpretation for Patient Specimens

Flu A	Flu B	RSV	SC2	RP	Result Interpretation	Action
+	-	-	-	+ or -	Influenza A detected	Report results to sender and appropriate public health authorities
-	+	-	-	+ or -	Influenza B detected	Report results to sender and appropriate public health authorities
-	-	+	-	+ or -	RSV detected	Report results to sender and appropriate public health authorities
-	-	-	+	+ or -	SARS-CoV-2 detected	Report results to sender and appropriate public health authorities
+	+	-	-	+ or -	Influenza A and Influenza B detected	Report results to sender and appropriate public health authorities
+	-	+	-	+ or -	Influenza A and RSV detected	Report results to sender and appropriate public health authorities
+	-	-	+	+ or -	Influenza A and SARS-CoV-2 detected	Report results to sender and appropriate public health authorities
-	+	+	-	+ or -	Influenza B and RSV detected	Report results to sender and appropriate public health authorities
-	+	-	+	+ or -	Influenza B and SARS-CoV-2 detected	Report results to sender and appropriate public health authorities
-	-	+	+	+ or -	RSV and SARS-CoV-2 detected	Report results to sender and appropriate public health authorities
+	+	+	-	+ or -	Influenza A, Influenza B, and RSV detected	Report results to sender and appropriate public health authorities
+	-	+	+	+ or -	Influenza A, RSV and SARS-CoV-2 detected	Report results to sender and appropriate public health authorities

Flu A	Flu B	RSV	SC2	RP	Result Interpretation	Action
-	+	+	+	+ or -	Influenza B, RSV and SARS-CoV-2 detected	Report results to sender and appropriate public health authorities
+	+	-	+	+ or -	Influenza A, Influenza B, and SARS-CoV-2 detected	Report results to sender and appropriate public health authorities
+	+	+	+	+ or -	Influenza A, Influenza B, RSV, and SARS-CoV-2 detected	Report results to sender and appropriate public health authorities
-	-	-	-	+	Negative	Report results to sender
-	-	-	-	-	Invalid	Repeat extraction and RT-PCR. If the repeated result remains invalid, consider collecting a new specimen from the patient

PERFORMANCE EVALUATION

1) Limit of Detection (LoD)

a) LoD Study for Anterior Nasal Swabs in 0.9% Saline

The analytical sensitivities of the Labcorp Seasonal Respiratory Virus RT-PCR Test were determined utilizing the virus strains listed in Table 4. Table 5 lists the associated stock concentrations in copies/µL and in $TCID_{50}$/µL. Virus stocks were diluted in 2-fold increments over the expected LoD concentration ranges using pooled negative anterior nasal swab specimens collected in saline. A total of 20 specimens of each virus at each dilution was tested. The results of the LoD study are summarized in Table 6. Table 7 summarizes the analytical sensitivities for each virus strain tested.

Table 4: Strains Used in LoD Determination

Viral Strain	Source	Catalog #	Lot #	Format
A/Nebraska/14/2018 (H1N1)	Microbiologics	Custom	D2013A	Culture Fluid
A/Hong Kong/2671/2019 (H3N2)	Virapur	Custom	C2030D	Culture Fluid
B/Colorado/06/2017 (Victoria)	Virapur	Custom	B1904S1	Culture Fluid
B/Phu ket/3073/2013 (Yamagata)	Virapur	Custom	B1904N	Culture Fluid
RSV A2	Virapur	Custom	K1907B	Culture Fluid
RSV B/Washington	Virapur	Custom	E1831C	Culture Fluid
SARS-CoV-2 USA-WA1/2020	BEI Resources	NR-52350	70033928	Heat-Inactivated Virus

Table 5: Viral Stock Concentrations

Viral Strain	Stock Concentration	
	$TCID_{50}$/µL	copies/µL
A/Nebraska/14/2018 (H1N1)	6.3×10^4	4.60×10^6
A/Hong Kong/2671/2019 (H3N2)	6.3×10^3	2.27×10^6

Viral Strain	Stock Concentration	
	$TCID_{50}$/µL	**copies/µL**
B/Colorado/06/2017 (Victoria)	1.4×10^5	1.13×10^6
B/Phu ket/3073/2013 (Yamagata)	1.4×10^5	7.23×10^6
RSV A2	6.3×10^3	4.99×10^6
RSV B Washington	4.6×10^3	4.98×10^6
SARS-CoV-2 USA-WA1/2020*	18	3.40×10^5

*titer determined prior to inactivation

Table 6: Limit of Detection Results

Viral Strain	Concentration		Positive / Total	% Detection	Mean Ct*
	copies/µL	**$TCID_{50}$/µL**			
A/Nebraska/14/2018 (H1N1)	12.50	0.1712	20 / 20	100.0	32.33
	6.25	0.0856	20 / 20	100.0	33.23
	3.13	0.0428	20 / 20	100.0	34.53
	1.56	**0.0214**	**20 / 20**	**100.0**	**35.59**
	0.78	0.0107	17 / 20	85.0	37.88
A/Hong Kong/2671/2019 (H3N2)	12.50	0.0347	20 / 20	100.0	31.90
	6.25	0.0173	20 / 20	100.0	32.81
	3.13	0.0087	20 / 20	100.0	33.65
	1.56	0.0043	20 / 20	100.0	35.16
	0.78	**0.0022**	**20 / 20**	**100.0**	**36.88**
	0.39	0.0011	3 / 20	15.0	39.08
	0.19	0.0005	0 / 20	0.0	N/A**
B/Colorado/06/2017 (Victoria)	3.13	0.3878	20 / 20	100.0	37.70
	1.56	**0.1939**	**19 / 20**	**95.0**	**38.27**
	0.78	0.0969	16 /20	80.0	38.90
	0.39	0.0485	7 / 20	35.0	39.43
	0.19	0.0242	1 / 20	5.0	N/A
B/Phuket/3073/2013 (Yamagata)	12.50	0.2420	20 / 20	100.0	31.22
	6.25	0.1210	20 / 20	100.0	32.10
	3.13	0.0605	20 / 20	100.0	33.35
	1.56	0.0303	20 / 20	100.0	34.34
	0.78	**0.0151**	**20 / 20**	**100.0**	**35.71**
	0.39	0.0076	7 / 20	35.0	38.78
	0.19	0.0038	3 / 20	15.0	39.91
RSV A2	12.50	0.0158	20 / 20	100.0	32.55
	6.25	0.0079	20 / 20	100.0	33.65
	3.13	0.0039	20 / 20	100.0	34.57
	1.56	**0.0020**	**20 / 20**	**100.0**	**36.21**
	0.78	0.0010	18 / 20	90.0	37.49
RSV B Washington	12.50	0.0115	20 / 20	100.0	35.06
	6.25	**0.0058**	**20 / 20**	**100.0**	**36.03**
	3.13	0.0029	18 / 20	90.0	37.31
	1.56	0.0014	13 /20	65.0	38.30
	0.78	0.0007	5 / 20	25.0	38.46

Viral Strain	Concentration		Positive / Total	% Detection	Mean Ct*
	copies/µL	$TCID_{50}$/µL			
SARS-CoV-2 USA-WA1/2020	12.50	0.00066	20 / 20	100.0	33.00
	6.25	0.00033	20 / 20	100.0	33.73
	3.13	0.00017	20 / 20	100.0	34.92
	1.56	**0.00008**	**20 / 20**	**100.0**	**36.10**
	0.78	0.00004	18 / 20	90.0	37.92

*calculated using only replicates returning a positive result
**not applicable

Table 7: LoD Summary for On-Panel Analytes in Anterior Nasal Swabs in 0.9% Saline

Virus Strain	Concentration		Detection Rate
	copies/µL	$TCID_{50}$/µL	
A/Nebraska/14/2018 (H1N1)	1.56	0.0214	100%
A/Hong Kong/2671/2019 (H3N2)	0.78	0.0022	100%
B/Colorado/06/2017 (Victoria)	1.56	0.1939	95%
B/Phuket/3073/2013 (Yamagata)	0.78	0.0151	100%
RSV A2	1.56	0.0020	100%
RSV B Washington	6.25	0.0058	100%
SARS-CoV-2 USA-WA1/2020	1.56	0.00008	100%

b) LoD Study for NP Swabs in VTM

The Labcorp Seasonal Respiratory Virus RT-PCR Test analytical sensitivities were also confirmed when testing NP specimens collected in VTM. The same virus strains and associated stock concentrations as described in Tables 4 and 5, respectively, were used for this study.

Virus stocks were diluted to the previously determined saline anterior nasal swab LoD concentrations (Table 7) using pooled negative NP swab specimens collected in VTM. A total of 20 replicates of each strain at the previously determined LoD were tested. All strains yielded a detection rate of 95% or greater thus demonstrating equivalence between NP specimens in VTM and anterior nasal swabs in saline. The results of the LoD study are summarized in Table 8.

Table 8: LoD Summary for NP Swabs in VTM

Virus Strain	Concentration (copies/µL)	Positive Replicates/Total	Detection Rate	Mean Ct*
A/Nebraska/14/2018 (H1N1)	1.56	19/20	95%	36.18
A/Hong Kong/2671/2019 (H3N2)	0.78	19/20	95%	36.21
B/Colorado/06/2017 (Victoria)	1.56	19/20	95%	33.42
B/Phu ket/3073/2013 (Yamagata)	0.78	20/20	100%	35.32
RSV A2	1.56	19/20	95%	35.50
RSV B Washington	6.25	19/20	95%	33.96
SARS-CoV-2 USA-WA1/2020	1.56	20/20	100%	34.49

* Ct values from negative replicates omitted from calculation

c) Co-formulated Limit of Detection

A co-formulated LoD study was performed for the Labcorp Seasonal Respiratory Virus RT-PCR Test. The Influenza A, Influenza B, and RSV strains with the lowest LoDs were combined with SARS-CoV-2 USA-WA1/2020 for testing. Strains were diluted to their respective LoD using pooled negative anterior nasal swab specimens collected in saline and 20 replicates were tested. The results of the co-formulated testing are summarized in Table 9. The assay LoDs for Flu A, Flu B, and SARS-CoV-2 were not affected by the multiplex testing. However, RSV demonstrated a drop in sensitivity.

Table 9: LoD Results for Flu A, Flu B, RSV, and SARS-CoV-2 Strain Co-formulation

Strain Combination	copies/µL	Positives / Total			
		Flu A	Flu B	RSV	SARS-CoV-2
A/Nebraska/14/2018	1.56	19 / 20	20 / 20	**2 / 20**	20 / 20
B/Colorado/06/2017	1.56				
RSV B Washington	6.25				
SARS-CoV-2 USA-WA1/2020	1.56				

The study was repeated removing the RSV strain (RSV B Washington) from the combination. The assay LoDs for Flu A, Flu B, and SARS-CoV-2 were not affected when the three targets were co-formulated. The results are summarized in Table 10.

Table 10: LoD Results for Flu A, Flu B and SARS-CoV-2 Strain Co-formulation

Strain Combination	copies/µL	Flu A		Flu B		SARS-CoV-2	
		Pos/ total	Ave. Ct	Pos/ total	Ave. Ct	Pos/ total	Ave. Ct
A/Nebraska/14/2018	1.56	20/20	35.94	20/20	34.60	20/20	35.78
B/Colorado/06/2017	1.56						
SARS-CoV-2 USA-WA1/2020	1.56						

2) Inclusivity (Analytical Sensitivity)

The Labcorp Seasonal Respiratory Virus RT-PCR Test primer and probe set sequences for SARS-CoV-2, influenza A and influenza B are identical to the CDC Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay (EUA201781) and, although the remaining Labcorp Seasonal Respiratory Virus RT-PCR Test reagents and workflow differ slightly from the CDC Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay, the differences are not expected to impact inclusivity of the device. Therefore, the inclusivity data for SARS-CoV-2, influenza A and influenza B provided by the CDC by Right of Reference can be leveraged to support inclusivity of the Labcorp Seasonal Respiratory Virus RT-PCR Test for these viral

targets. Please refer to the CDC Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay Instructions for Use for detailed in silico and wet testing SARS-CoV-2, influenza A and influenza B inclusivity information.

Additional in silico inclusivity analyses were performed by Labcorp to assess the impact of the recently emerged SARS-CoV-2 variants as well as RSV variants on target detection. The VSEARCH usearch_global algorithm was used to align the SARS-CoV-2 and RSV test primers and probes to the reference sequences (as of April 24, 2022) of the GISAID and NCBI databases, respectively. Since several mutations and variants of SARS-CoV-2 and RSV were identified as prevalent and/or potentially clinically significant, Labcorp performed wet testing using clinical isolates to assess the impact of the mutation or variant on the test performance.

Inclusivity of the Labcorp Seasonal Respiratory Virus RT-PCR Test was demonstrated by wet testing multiple strains of Influenza A (H1N1 and H3N2), Influenza B (Yamagata and Victoria lineages), RSV (A and B) and SARS-CoV-2. Virus stocks were individually diluted to 3X the LoD (Flu A, Flu B, and SARS-CoV-2 each at 4.58 cp/µL and RSV at 18.75 cp/µL) using pooled negative nasal swab specimens and tested in triplicate. All strains were detected at 3X LoD except where otherwise noted. The results of the inclusivity testing are summarized in Table 11. The corresponding tested concentrations in $TCID_{50}$/µL are also listed in the table.

Table 11: Summary of Inclusivity Results by Wet Testing

Viral Strain	$TCID_{50}$/µL	Positive Replicates / Total			
		Flu A	Flu B	RSV	SARS-CoV-2
A/California/07/09 (H1N1)	0.305	3 / 3	0 / 3	0 / 3	0 / 3
A/Canada/6294/09 (H1N1)	0.227	3 / 3	0 / 3	0 / 3	0 / 3
A/Mexico/4108/09 (H1N1)	0.021	3 / 3	0 / 3	0 / 3	0 / 3
A/Michigan/45/15 (H1N1)	0.009	3 / 3	0 / 3	0 / 3	0 / 3
A/Singapore/63/04 (H1N1)	0.010	3 / 3	0 / 3	0 / 3	0 / 3
Guangdong-Maonan/SWL 1536/19 (H1N1)	0.00057	3 / 3	0 / 3	0 / 3	0 / 3
Brisbane/02/18 (H1N1)	0.00002	3 / 3	0 / 3	0 / 3	0 / 3
NY/02/09 (H1N1)	0.00253	3 / 3	0 / 3	0 / 3	0 / 3
Solomon Island/03/06 (H1N1)	0.00007	3 / 3	0 / 3	0 / 3	0 / 3
New Caledonia/20/99 (H1N1)	0.00012*	3 / 3	0 / 3	0 / 3	0 / 3
A/HongKong/4801/14 (H3N2)	0.203	3 / 3	0 / 3	0 / 3	0 / 3
A/Perth/16/09 (H3N2)	0.071	3 / 3	0 / 3	0 / 3	0 / 3
A/Switzerland/9715293/13 (H3N2)	0.071	3 / 3	0 / 3	0 / 3	0 / 3
A/Texas/50/12 (H3N2)	0.210	3 / 3	0 / 3	0 / 3	0 / 3
A/Wisconsin/67/05 (H3N2)	0.491	3 / 3	0 / 3	0 / 3	0 / 3
Kansas/14/17 (H3N2)	0.00075	3 / 3	0 / 3	0 / 3	0 / 3
Singapore/INFIMH-16-0019/16 (H3N2)	0.00111	3 / 3	0 / 3	0 / 3	0 / 3
South Australia/55/14 (H3N2)	0.00015	3 / 3	0 / 3	0 / 3	0 / 3
Victoria/361/11 (H3N2)	0.00004	3 / 3	0 / 3	0 / 3	0 / 3
A/Stockholm/6/14 (H3N2) – 3X LoD	0.000008	2 / 3	0 / 3	0 / 3	0 / 3
A/Stockholm/6/14 (H3N2) – 3X LoD (repeat test)	0.000008	3 / 3	0 / 3	0 / 3	0 / 3
A/Stockholm/6/14 (H3N2) – 4XLoD**	0.000011	3 / 3	0 / 3	0 / 3	0 / 3

Viral Strain	$TCID_{50}$/µL	Positive Replicates / Total			
		Flu A	Flu B	RSV	SARS-CoV-2
A/California/7/04 (H3N2) – 3X LoD	0.000951	3 / 3	0 / 3	0 / 3	0 / 3
B/Alabama/2/17 (Victoria)	0.006	0 / 3	3 / 3	0 / 3	0 / 3
B/Brisbane/60/2008 (Victoria)	0.006	0 / 3	3 / 3	0 / 3	0 / 3
B/Florida/78/2015 (Victoria)	0.238	0 / 3	3 / 3	0 / 3	0 / 3
B/Washington/02/2019 (Victoria)	22.003	0 / 3	3 / 3	0 / 3	0 / 3
B/Wisconsin/1/2010 (Yamagata)	0.169	0 / 3	3 / 3	0 / 3	0 / 3
B/Utah/9/2014 (Yamagata)	0.001	0 / 3	3 / 3	0 / 3	0 / 3
RSV A 3/2015 Isolate #3	0.002	0 / 3	0 / 3	3 / 3	0 / 3
RSV A 2014 Isolate 341	0.005	0 / 3	0 / 3	3 / 3	0 / 3
RSV A 2013 Isolate	0.0013	0 / 3	0 / 3	3 / 3	0 / 3
RSV A 2006 Isolate	0.0003	0 / 3	0 / 3	3 / 3	0 / 3
RSV B CH93(18)-18	0.0037	0 / 3	0 / 3	3 / 3	0 / 3
RSV B 3/2015 Isolate #1	0.0026	0 / 3	0 / 3	3 / 3	0 / 3
RSV B WV/14617/85	0.0054	0 / 3	0 / 3	3 / 3	0 / 3
SARS-CoV-2 (Hong Kong/VM20001061/2020)	0.006	0 / 3	0 / 3	0 / 3	3 / 3
SARS-CoV-2 (Isolate: Italy-INMI1)	0.102	0 / 3	0 / 3	0 / 3	3 / 3
SARS-CoV-2 Variant B.1.351 SA	0.0005	0 / 3	0 / 3	0 / 3	3 / 3
SARS-CoV-2 Variant B.1.1.7 ENG	0.0004	0 / 3	0 / 3	0 / 3	3 / 3
SARS-CoV-2 Variant BA.2***	-	0/20	0/20	0/20	20/20

* Viral lysate reported in ng/µL

** Concentration in $TCID_{50}$/µL when specimen is diluted to 6.11 cp/µL (4x LoD)

*** 20 clinical samples were first identified as positive for SARS-CoV-2 by an EUA authorized SARS-CoV-2 assay, then sequenced as SARS-CoV-2 BA.2 variant and later wet tested using the Labcorp Seasonal Respiratory Virus RT-PCR Test as shown above.

3) Cross-Reactivity

Cross-reactivity of the Labcorp Seasonal Respiratory Virus RT-PCR Test was evaluated by testing a panel of 44 organisms consisting of 22 virus, 19 bacteria, and two fungus strains representing common respiratory pathogens or flora commonly present in respiratory tract. Whole organisms were tested except for human coronavirus HKU1. Viruses were tested at concentrations of $\geq 1x10^5$ copies/mL or $TCID_{50}$/mL, except where otherwise noted. Bacteria and fungus strains were tested at a concentration of $1x10^6$ copies/mL, cfu/mL or IFU/mL, except where noted. The following target viruses were used in the cross-reactivity study: A/Nebraska/14/2018, B/Colorado/06/2017, RSV A2, RSV B Washington, and SARS-CoV-2 USA-WA1/2020 to evaluate the on-panel viruses cross-reactivity. Organisms were diluted to the listed concentrations using pooled negative anterior nasal swab specimens (saline) and tested in triplicate. No cross-reactivity with common non-target respiratory organisms was detected and target viruses only yielded a positive test result for the appropriate virus. The results are summarized in Table 12.

Table 12: Cross-Reactivity with Common Respiratory Organisms

Organism	Concentration	Positive Replicates / Total			
		Flu A	Flu B	RSV	SARS-CoV-2
Influenza A Virus	1 x 10^6 cp/mL	3 / 3	0 / 3	0 / 3	0 / 3
Influenza B Virus	1 x 10^6 cp/mL	0 / 3	3 / 3	0 / 3	0 / 3
Respiratory Syncytial Virus A	1 x 10^6 cp/mL	0 / 3	0 / 3	3 / 3	0 / 3
Respiratory Syncytial Virus B	1 x 10^6 cp/mL	0 / 3	0 / 3	3 / 3	0 / 3
SARS-CoV-2	1 x 10^6 cp/mL	0 / 3	0 / 3	0 / 3	3 / 3
SARS Coronavirus	1 x 10^4 $TCID_{50}$/mL	0 / 3	0 / 3	0 / 3	0 / 3
Bordetella pertussis	1 x 10^6 cfu/mL	0 / 3	0 / 3	0 / 3	0 / 3
Candida albicans	1 x 10^6 cfu/mL	0 / 3	0 / 3	0 / 3	0 / 3
Chlamydophila pneumoniae	1 x 10^6 IFU/mL	0 / 3	0 / 3	0 / 3	0 / 3
Corynebacterium diphtheriae	1 x 10^6 cfu/mL	0 / 3	0 / 3	0 / 3	0 / 3
Escherichia coli	1 x 10^6 cfu/mL	0 / 3	0 / 3	0 / 3	0 / 3
Haemophilus influenzae	1 x 10^6 cfu/mL	0 / 3	0 / 3	0 / 3	0 / 3
Lactobacillus acidophilus	1 x 10^6 cfu/mL	0 / 3	0 / 3	0 / 3	0 / 3
Legionella longbeachae	1 x 10^6 cfu/mL	0 / 3	0 / 3	0 / 3	0 / 3
Legionella pneumophila	1 x 10^6 cfu/mL	0 / 3	0 / 3	0 / 3	0 / 3
Moraxella catarrhalis	1 x 10^6 cfu/mL	0 / 3	0 / 3	0 / 3	0 / 3
Mycoplasma pneumoniae	1 x 10^6 cfu/mL	0 / 3	0 / 3	0 / 3	0 / 3
Neisseria lactamica	1 x 10^6 cfu/mL	0 / 3	0 / 3	0 / 3	0 / 3
Neisseria meningitidis	1 x 10^6 cfu/mL	0 / 3	0 / 3	0 / 3	0 / 3
Pneumocystis carinii	1 x 10^6 cp/mL	0 / 3	0 / 3	0 / 3	0 / 3
Pseudomonas aeruginosa	1 x 10^6 cfu/mL	0 / 3	0 / 3	0 / 3	0 / 3
Staphylococcus epidermidis	1 x 10^6 cfu/mL	0 / 3	0 / 3	0 / 3	0 / 3
Streptococcus pneumoniae	1 x 10^6 cfu/mL	0 / 3	0 / 3	0 / 3	0 / 3
Streptococcus salivarius	1 x 10^6 cfu/mL	0 / 3	0 / 3	0 / 3	0 / 3
Human Coronavirus 229E	1 x 10^5 $TCID_{50}$/mL	0 / 3	0 / 3	0 / 3	0 / 3
Adenovirus Type 1	1 x 10^5 $TCID_{50}$/mL	0 / 3	0 / 3	0 / 3	0 / 3
Adenovirus Type 7	1 x 10^5 $TCID_{50}$/mL	0 / 3	0 / 3	0 / 3	0 / 3
Cytomegalovirus	1 x 10^5 cp/mL	0 / 3	0 / 3	0 / 3	0 / 3
Epstein Barr Virus	1 x 10^5 cp/mL	0 / 3	0 / 3	0 / 3	0 / 3
Enterovirus D68	1 x 10^5 $TCID_{50}$/mL	0 / 3	0 / 3	0 / 3	0 / 3
Human coronavirus HKU1*	1 x 10^4 cp/mL	0 / 3	0 / 3	0 / 3	0 / 3
Human Metapneumovirus	1 x 10^5 $TCID_{50}$/mL	0 / 3	0 / 3	0 / 3	0 / 3
Mycobacterium tuberculosis	> 5 x 10^3 cfu/mL	0 / 3	0 / 3	0 / 3	0 / 3
MERS-coronavirus	1 x 10^5 $TCID_{50}$/mL	0 / 3	0 / 3	0 / 3	0 / 3
Human Coronavirus NL63	1 x 10^4 $TCID_{50}$/mL	0 / 3	0 / 3	0 / 3	0 / 3
Human Coronavirus OC43	1 x 10^4 $TCID_{50}$/mL	0 / 3	0 / 3	0 / 3	0 / 3
Human Parainfluenza Virus 1	1 x 10^5 $TCID_{50}$/mL	0 / 3	0 / 3	0 / 3	0 / 3
Human Parainfluenza Virus 2	1 x 10^5 $TCID_{50}$/mL	0 / 3	0 / 3	0 / 3	0 / 3
Human Parainfluenza Virus 3	1 x 10^5 $TCID_{50}$/mL	0 / 3	0 / 3	0 / 3	0 / 3
Human Parainfluenza Virus 4	1 x 10^4 $TCID_{50}$/mL	0 / 3	0 / 3	0 / 3	0 / 3
Human rhinovirus 61	1 x 10^5 $TCID_{50}$/mL	0 / 3	0 / 3	0 / 3	0 / 3
Staphylococcus aureus	1 x 10^6 cfu/mL	0 / 3	0 / 3	0 / 3	0 / 3
Streptococcus pyogenes	1 x 10^6 cfu/mL	0 / 3	0 / 3	0 / 3	0 / 3

*isolated RNA - synthetic genomic construct

4) Microbial Interference

Assay target viruses were tested in the presence of the organisms listed in Table 13. All potentially interfering organisms were intact except for human coronavirus HKU1. Testing was performed by co-spiking viruses A/Nebraska/14/2018, B/Colorado/06/2017, and SARS-CoV-2 USA-WA1/2020 (at 3X the LoD – 4.68 cp/µL each) into specimens containing each potentially interfering organism. RSV A2 (Virapur Lot K1907B) and RSV B Washington was tested individually at 3X the LoD (18.75 cp/µL) in the presence of each potentially interfering organism. Non-target viruses were tested at concentrations of $1x10^5$ copies/mL or $TCID_{50}$/mL, except where otherwise noted. Bacteria and fungus strains were tested at concentrations of $1x10^6$ copies/mL, cfu/mL or IFU/mL, except where noted. Target viruses and potentially interfering organisms were diluted using pooled negative anterior nasal swab specimens (saline) and tested in triplicate. All target viruses were detected at 3X LoD in the presence of the other listed organisms. The results are summarized in Table 13.

Table 13: Interference with Other Common Respiratory Organisms

Organism	Concentration	Positive Replicates / Total				
		Flu A	Flu B	RSV-A	RSV-B	SARS-CoV-2
None	N/A	3 / 3	3 / 3	3 / 3	3 / 3	3 / 3
SARS Coronavirus	1 x 10^4 $TCID_{50}$/mL	3 / 3	3 / 3	3 / 3	3 / 3	3 / 3
Bordetella pertussis	1 x 10^6 cfu/mL	3 / 3	3 / 3	3 / 3	3 / 3	3 / 3
Candida albicans	1 x 10^6 cfu/mL	3 / 3	3 / 3	3 / 3	3 / 3	3 / 3
Chlamydophila pneumoniae	1 x 10^6 IFU/mL	3 / 3	3 / 3	3 / 3	3 / 3	3 / 3
Corynebacterium diphtheriae	1 x 10^6 cfu/mL	3 / 3	3 / 3	3 / 3	3 / 3	3 / 3
Escherichia coli	1 x 10^6 cfu/mL	3 / 3	3 / 3	3 / 3	3 / 3	3 / 3
Haemophilus influenzae	1 x 10^6 cfu/mL	3 / 3	3 / 3	3 / 3	3 / 3	3 / 3
Lactobacillus acidophilus	1 x 10^6 cfu/mL	3 / 3	3 / 3	3 / 3	3 / 3	3 / 3
Legionella longbeachae	1 x 10^6 cfu/mL	3 / 3	3 / 3	3 / 3	3 / 3	3 / 3
Legionella pneumophila	1 x 10^6 cfu/mL	3 / 3	3 / 3	3 / 3	3 / 3	3 / 3
Moraxella catarrhalis	1 x 10^6 cfu/mL	3 / 3	3 / 3	3 / 3	3 / 3	3 / 3
Mycoplasma pneumoniae	1 x 10^6 cfu/mL	3 / 3	3 / 3	3 / 3	3 / 3	3 / 3
Neisseria lactamica	1 x 10^6 cfu/mL	3 / 3	3 / 3	3 / 3	3 / 3	3 / 3
Neisseria meningitidis	1 x 10^6 cfu/mL	3 / 3	3 / 3	3 / 3	3 / 3	3 / 3
Pneumocystis carinii	1 x 10^6 nuclei/mL	3 / 3	3 / 3	3 / 3	3 / 3	3 / 3
Pseudomonas aeruginosa	1 x 10^6 cfu/mL	3 / 3	3 / 3	3 / 3	3 / 3	3 / 3
Staphylococcus epidermidis	1 x 10^6 cfu/mL	3 / 3	3 / 3	3 / 3	3 / 3	3 / 3
Streptococcus pneumoniae	1 x 10^6 cfu/mL	3 / 3	3 / 3	3 / 3	3 / 3	3 / 3
Streptococcus salivarius	1 x 10^6 cfu/mL	3 / 3	3 / 3	3 / 3	3 / 3	3 / 3
Human Coronavirus 229E	1 x 10^5 $TCID_{50}$/mL	3 / 3	3 / 3	3 / 3	3 / 3	3 / 3
Adenovirus Type 1	1 x 10^5 $TCID_{50}$/mL	3 / 3	3 / 3	3 / 3	3 / 3	3 / 3
Adenovirus Type 7	1 x 10^5 $TCID_{50}$/mL	3 / 3	3 / 3	3 / 3	3 / 3	3 / 3
Cytomegalovirus	1 x 10^5 cp/mL	3 / 3	3 / 3	3 / 3	3 / 3	3 / 3
Epstein Barr Virus	1 x 10^5 cp/mL	3 / 3	3 / 3	3 / 3	3 / 3	3 / 3
Enterovirus D68	1 x 10^5 $TCID_{50}$/mL	3 / 3	3 / 3	3 / 3	3 / 3	3 / 3
Human coronavirus HKU1*	1 x 10^4 cp/mL	3 / 3	3 / 3	3 / 3	3 / 3	3 / 3

Organism	Concentration	Positive Replicates / Total				
		Flu A	Flu B	RSV-A	RSV-B	SARS-CoV-2
Human Metapneumovirus	1 x 10^5 $TCID_{50}$/mL	3 / 3	3 / 3	3 / 3	3 / 3	3 / 3
Mycobacterium tuberculosis	> 5 x 10^3 cfu/mL	3 / 3	3 / 3	3 / 3	3 / 3	3 / 3
MERS-coronavirus	1 x 10^5 $TCID_{50}$/mL	3 / 3	3 / 3	3 / 3	3 / 3	3 / 3
Human Coronavirus NL63	1 x 10^4 $TCID_{50}$/mL	3 / 3	3 / 3	3 / 3	3 / 3	3 / 3
Human Coronavirus OC43	1 x 10^4 $TCID_{50}$/mL	3 / 3	3 / 3	3 / 3	3 / 3	3 / 3
Human Parainfluenza Virus 1	1 x 10^5 $TCID_{50}$/mL	3 / 3	3 / 3	3 / 3	3 / 3	3 / 3
Human Parainfluenza Virus 2	1 x 10^5 $TCID_{50}$/mL	3 / 3	3 / 3	3 / 3	3 / 3	3 / 3
Human Parainfluenza Virus 3	1 x 10^5 $TCID_{50}$/mL	3 / 3	3 / 3	3 / 3	3 / 3	3 / 3
Human Parainfluenza Virus 4	1 x 10^4 $TCID_{50}$/mL	3 / 3	3 / 3	3 / 3	3 / 3	3 / 3
Human rhinovirus 61	1 x 10^5 $TCID_{50}$/mL	3 / 3	3 / 3	3 / 3	3 / 3	3 / 3
Staphylococcus aureus	1 x 10^6 cfu/mL	3 / 3	3 / 3	3 / 3	3 / 3	3 / 3
Streptococcus pyogenes	1 x 10^6 cfu/mL	3 / 3	3 / 3	3 / 3	3 / 3	3 / 3

*isolated RNA - synthetic genomic construct

5) Collection Media Equivalency

A collection media equivalency study was performed between Copan UTM and the following claimed media types using negative anterior nasal swab matrix: saline, CDC VTM and Remel M4RT. Specimens were generated by co-spiking viral strains A/Nebraska/14/2018, B/Colorado/06/2017, and SARS-CoV-2 USA-WA1/2020 separately into individual negative anterior nasal swab specimens collected in Copan UTM, CDC VTM, Remel 4RT, or saline to yield concentrations at 2X the LoD (3.12 cp/µL each virus) or 5X the LoD (7.80 cp/µL each virus). RSV B Washington was separately diluted into individual negative anterior nasal swab specimens collected in Copan UTM, CDC VTM, Remel 4RT, or saline to yield concentrations at 2X the LoD (12.50 cp/µL) or 5X the LoD (31.25 cp/µL). Five 2X LoD specimen replicates and five 5X LoD specimen replicates containing Flu A/B/SARS-CoV-2 or RSV in each of the collection media were tested. Five negative specimen replicates in each collection medium were also included to monitor specimen contamination.

The negative replicates tested in each collection medium were negative for all viral targets. All replicates containing virus were positive for the appropriate targets. See the Table 14 for the percent detected values and mean Ct values for each target concentration in each collection medium.

Table 14: Percent Detected and Mean Ct Values

Analyte	Media	Flu A		Flu B		RSV		SARS-CoV-2		RNase P	
		% Detect.	Mean Ct	% Detect.	Mean Ct	% Detect.	Mean Ct	% Detect.	Mean Ct	% Detect.	Mean Ct
Flu A/B-SCV-2 2X LOD	Copan UTM	100.0	31.47	100.0	33.20	N/A	N/A	100.0	34.31	100.0	28.46
Flu A/B-SCV-2 2X LOD	CDC VTM	100.0	31.04	100.0	33.35	N/A	N/A	100.0	34.45	100.0	29.72

Analyte	Media	Flu A		Flu B		RSV		SARS-CoV-2		RNase P	
		% Detect.	Mean Ct	% Detect.	Mean Ct	% Detect.	Mean Ct	% Detect.	Mean Ct	% Detect.	Mean Ct
Flu A/B-SCV-2 2X LOD	Remel M4RT	100.0	31.63	100.0	34.16	N/A	N/A	100.0	35.09	100.0	28.34
Flu A/B-SCV-2 2X LOD	Saline	100.0	32.41	100.0	34.74	N/A	N/A	100.0	35.35	100.0	30.54
RSV 2X LOD	Copan UTM	N/A	N/A	N/A	N/A	100.0	32.03	N/A	N/A	100.0	31.19
RSV 2X LOD	CDC VTM	N/A	N/A	N/A	N/A	100.0	32.20	N/A	N/A	100.0	31.15
RSV 2X LOD	Remel M4RT	N/A	N/A	N/A	N/A	100.0	32.33	N/A	N/A	100.0	32.26
RSV 2X LOD	Saline	N/A	N/A	N/A	N/A	100.0	33.68	N/A	N/A	100.0	30.30
Flu A/B-SCV-2 5X LOD	Copan UTM	100.0	30.28	100.0	32.83	N/A	N/A	100.0	33.60	100.0	32.36
Flu A/B-SCV-2 5X LOD	CDC VTM	100.0	29.63	100.0	32.04	N/A	N/A	100.0	33.15	100.0	31.03
Flu A/B-SCV-2 5X LOD	Remel M4RT	100.0	31.23	100.0	33.86	N/A	N/A	100.0	34.68	80.0	31.10
Flu A/B-SCV-2 5X LOD	Saline	100.0	30.30	100.0	33.80	N/A	N/A	100.0	33.91	100.0	32.34
RSV 5X LOD	Copan UTM	N/A	N/A	N/A	N/A	100.0	31.28	N/A	N/A	100.0	33.82
RSV 5X LOD	CDC VTM	N/A	N/A	N/A	N/A	100.0	31.21	N/A	N/A	100.0	33.17
RSV 5X LOD	Remel M4RT	N/A	N/A	N/A	N/A	100.0	31.69	N/A	N/A	100.0	34.02
RSV 5X LOD	Saline	N/A	N/A	N/A	N/A	100.0	31.66	N/A	N/A	100.0	30.90
Negative	Copan UTM	0.00	N/A	0.00	N/A	0.00	N/A	0.00	N/A	100.0	26.55
Negative	CDC VTM	0.00	N/A	0.00	N/A	0.00	N/A	0.00	N/A	100.0	28.35
Negative	Remel M4RT	0.00	N/A	0.00	N/A	0.00	N/A	0.00	N/A	100.0	28.65
Negative	Saline	0.00	N/A	0.00	N/A	0.00	N/A	0.00	N/A	100.0	29.74

The mean Ct values for the 2X and 5X LOD specimens diluted in CDC VTM, Remel 4RT, and saline differed by no more than 3.0 for all targets as compared to the specimens diluted in Copan UTM. See Table 15 below for Ct value standard deviations (SD) and mean Ct differences from the Copan UTM results.

Table 15: Ct Value SDs and Mean Ct Differences

Analyte	Media	Flu A		Flu B		RSV		SARS-CoV-2		RNase P	
		SD	Ct Diff	SD	Ct Diff	SD	Ct Diff	SD	Ct Diff	SD	Ct Diff
Flu A/B-SCV-2 2X LOD	Copan UTM	0.26	N/A	0.92	N/A	N/A	N/A	0.72	N/A	1.43	N/A
Flu A/B-SCV-2 2X LOD	CDC VTM	0.36	-0.43	0.33	0.15	N/A	N/A	0.31	0.14	0.51	1.26
Flu A/B-SCV-2 2X LOD	Remel M4RT	0.36	0.16	0.29	0.96	N/A	N/A	0.72	0.78	1.08	-0.12
Flu A/B-SCV-2 2X LOD	Saline	0.24	0.94	0.25	1.54	N/A	N/A	0.48	1.04	1.18	2.08
RSV 2X LOD	Copan UTM	N/A	N/A	N/A	N/A	0.48	N/A	N/A	N/A	2.02	N/A
RSV 2X LOD	CDC VTM	N/A	N/A	N/A	N/A	0.46	0.17	N/A	N/A	0.93	-0.04
RSV 2X LOD	Remel M4RT	N/A	N/A	N/A	N/A	1.21	0.3	N/A	N/A	1.53	1.07
RSV 2X LOD	Saline	N/A	N/A	N/A	N/A	0.60	1.65	N/A	N/A	1.40	-0.89
Flu A/B-SCV-2 5X LOD	Copan UTM	0.64	N/A	0.66	N/A	N/A	N/A	0.39	N/A	0.55	N/A
Flu A/B-SCV-2 5X LOD	CDC VTM	0.24	-0.65	1.00	-0.79	N/A	N/A	0.31	-0.45	0.58	-1.33
Flu A/B-SCV-2 5X LOD	Remel M4RT	1.12	0.95	1.05	1.03	N/A	N/A	1.44	1.08	0.86	-1.26
Flu A/B-SCV-2 5X LOD	Saline	0.54	0.02	0.24	0.97	N/A	N/A	0.29	0.31	0.47	-0.02
RSV 5X LOD	Copan UTM	N/A	N/A	N/A	N/A	0.64	N/A	N/A	N/A	0.56	N/A
RSV 5X LOD	CDC VTM	N/A	N/A	N/A	N/A	0.28	-0.07	N/A	N/A	2.42	-0.65
RSV 5X LOD	Remel M4RT	N/A	N/A	N/A	N/A	0.46	0.41	N/A	N/A	1.89	0.2
RSV 5X LOD	Saline	N/A	N/A	N/A	N/A	0.91	0.38	N/A	N/A	2.59	-2.92

These results indicate that the assay performs similarly in the various collection media. Therefore, even though the analytical and clinical studies were not performed using all collection media, it is expected that similar results would have been obtained if each medium was used for all validation parameters.

6) Co-infection (Competitive Interference)

To evaluate coinfection inhibition, two target strains were combined for testing such that one was at a low concentration (3X LoD) and one was at a high concentration (10^6 copies/mL). Specimens were tested in triplicate. The strains utilized are listed in Table 16 and were diluted in pooled negative anterior nasal swab specimens (saline). Inhibition was observed for Flu A, RSV A, and RSV B at 3X LoD in the presence of high levels of Flu B (Table 16).

Table 16: Co-infection with an Interfering Target at 10^6 copies/mL

Target At 3x LoD	Interfering Targets (10^6 copies/mL)					
	None	Flu A	Flu B	RSV A	RSV B	Sars-CoV-2
	Positive Replicates / Total					
A/Nebraska/14/2018	3 / 3	N/A*	**1 / 3**	3 / 3	3 / 3	3 / 3
B/Colorado/06/2017	3 / 3	3 / 3	N/A	3 / 3	3 / 3	3 / 3
RSV A2	3 / 3	3 / 3	**0 / 3**	N/A	N/A	3 / 3
RSV B Washington	3 / 3	3 / 3	**1 / 3**	N/A	N/A	3 / 3
SARS-CoV-2 USA-WA1/2020	3 / 3	3 / 3	3 / 3	3 / 3	3 / 3	N/A
None	0 / 3	3 / 3	3 / 3	3 / 3	3 / 3	3 / 3

*Not applicable

Testing was performed again with Flu A, RSV A, and RSV B at 3X LoD in the presence of Flu B at 10^5 copies/mL (Table 17). No inhibition was observed at this concentration of Flu B.

Table 17: Co-infection with an Interfering Target at 10^5 copies/mL

Low Target	Interfering Target	Positive Replicates / Total
A/Nebraska/14/2018	Flu B 10^5 copies/mL	3 / 3
RSV A2		3 / 3
RSV B Washington		3 / 3

7) ***Interfering Substances (Endogenous and Exogenous)***

Endogenous and exogenous substances that may be present in respiratory specimens were evaluated for potential interference in the Labcorp Seasonal Respiratory Virus RT-PCR Test. Testing was performed by co-spiking A/Nebraska/14/2018, B/Colorado/06/2017, and SARS-CoV-2 USA-WA1/2020 (at 3X the LoD – 4.68 cp/µL each) into specimens separately containing the substances listed in Table 18. RSV B Washington was spiked individually at 3X the LoD (18.75 cp/µL) in the presence of each substance. Target viruses and potentially interfering substances were diluted to the listed concentrations using pooled negative anterior nasal swab specimens (saline) and tested in triplicate. Except for Afrin, none of the other substances inhibited the assay at the concentrations tested. Flu B, RSV, and SARS-CoV-2 were detectable in the presence of 15% v/v Afrin, whereas Flu A replicates were all detectable when the Afrin concentration was at 5% v/v. The results are summarized in Table 18.

Table 18: Interference with Endogenous and Exogenous Substances

Substance	Description/ Active Ingredient	Conc. in Specimen	Positive Replicates / Total				
			Flu A	Flu B	RSV	SARS-CoV-2	None
Neo-Synephrine	Phenylephrine hydrochloride 0.5%	15% v/v	3 / 3	3 / 3	3 / 3	3 / 3	0 / 3
Afrin	Oxymetazoline hydrochloride 0.05%	5% v/v	3 / 3	3 / 3	3 / 3	3 / 3	0 / 3

Substance	Description/ Active Ingredient	Conc. in Specimen	Positive Replicates / Total				
			Flu A	Flu B	RSV	SARS-CoV-2	None
Afrin	Oxymetazoline hydrochloride 0.05%	10 % v/v	0 / 3	NT**	NT	NT	NT
Afrin	Oxymetazoline hydrochloride 0.05%	15% v/v	1/ 3	3 / 3	3 / 3	3 / 3	0/3
Saline Nasal Spray	NaCl (0.65%), phenylcarbinol & benzalkonium chloride	15% v/v	3 / 3	3 / 3	3 / 3	3 / 3	0 / 3
Zicam Nasal Spray	Galphimia glauca, Histaminum hydrochloricum, Luffa operculata, Sulpher	15% v/v	3 / 3	3 / 3	3 / 3	3 / 3	0 / 3
Flonase	Fluticasone propionate 50mcg	2.5% v/v	3 / 3	3 / 3	3 / 3	3 / 3	0 / 3
Rhinocort	Budesonide 32mcg	5% v/v	3 / 3	3 / 3	3 / 3	3 / 3	0 / 3
Nasacort	Triamcinolone acetonide 55mcg	2.5% v/v	3 / 3	3 / 3	3 / 3	3 / 3	0 / 3
Nasal Corticosteroid	Dexamethasone 0.1 mg/mL	10 mcg/mL	3 / 3	3 / 3	3 / 3	3 / 3	0 / 3
Nasal Corticosteroid	Mometasone furoate 50mcg	5% v/v	3 / 3	3 / 3	3 / 3	3 / 3	0 / 3
Qnasl	Beclomethasone dipropionate 80mcg	5% v/v	3 / 3	3 / 3	3 / 3	3 / 3	0 / 3
Chloraseptic max	Benzocaine 15mg, Menthol 10mg	1% w/v	3 / 3	3 / 3	3 / 3	3 / 3	0 / 3
Antibiotic nasal ointment	Mupirocin 20mg/g	10 mg/mL	3 / 3	3 / 3	3 / 3	3 / 3	0 / 3
Relenza	Zanamivir 5mg	5 mg/mL	3 / 3	3 / 3	3 / 3	3 / 3	0 / 3
Antiviral Drug	Oseltamivir phosphate 6mg/mL	10 mcg/mL	3 / 3	3 / 3	3 / 3	3 / 3	0 / 3
Antibiotic, systemic	Tobramycin (40mg)	2 mg/mL	3 / 3	3 / 3	3 / 3	3 / 3	0 / 3
FluMist*	Live intranasal influenza virus	N/A	N/A	N/A	N/A	N/A	N/A
Ayr	Nasal Gel	1% w/v	3 / 3	3 / 3	3 / 3	3 / 3	0 / 3
NasoGEL	Nasal Gel	0.5% w/v	3 / 3	3 / 3	3 / 3	3 / 3	0 / 3
Mucin	Bovine Sub-maxillary Gland	0.1 mg/mL	3 / 3	3 / 3	3 / 3	3 / 3	0 / 3
Mucin	Bovine Sub-maxillary Gland	2.5 mg/mL*	3 / 3	3 / 3	3 / 3	3 / 3	0/3
Blood	Human	2% v/v	3 / 3	3 / 3	3 / 3	3 / 3	0 / 3

*FluMist was not available and therefore could not be tested
**NT= Not tested

8) Shipping Specimen Stability

a) Winter Temperature Excursion:

To extend the shipping stability of SARS-CoV-2, Influenza A, Influenza B, and RSV specimens when using the Labcorp COVID-19+Flu+RSV Test Home Collection Kit, a winter stability study was performed (Tables 19-21) extending the FDA recommended temperature profile with an additional 72 hours storage at room temperature.

Table 19: Winter temperature excursion

Temperature	Cycle Period	Cycle Period (Hours)	Total Time (Hours)
-10°C	1	8	8
18°C	2	4	12
-10°C	3	2	14
10°C	4	36	50
-10°C	5	6	56
Room Temperature	6	72	128

Stability specimens were generated by co-spiking viral strains A/Nebraska/14/2018, B/Colorado/06/2017, and SARS-CoV-2 USA-WA1/2020 into individual negative anterior nasal swab specimens (saline) to yield concentrations at 2X the LoD (3.12 cp/µL each virus) or 10X the LoD (15.6 cp/µL each virus). RSV B Washington was diluted into individual negative anterior nasal swab specimens (saline) to yield concentrations at 2X the LoD (12.50 cp/µL) or 10X the LoD (62.50 cp/µL). Twenty 2X LoD specimen replicates and ten 10X LoD specimen replicates containing Flu A/B/ SARS-CoV-2 or RSV were subjected to the winter profile. Ten negative specimen replicates were also included to monitor specimen contamination.

Replicates were tested at 0, 56 and 128 hours for the extended winter profile using the Labcorp Seasonal Respiratory Virus RT-PCR Test. See Tables 20 and 21 for a summary of the 2X LoD and 10X LoD specimen results, respectively. All replicates remained positive during the excursions except for RSV which had 19 positive 2X LoD replicates after each storage time point. The mean Ct values at T=56 hours total and at T=128 hours total for all targets were no greater than 3.0 Ct more than at time 0, indicating acceptable specimen stability under the conditions tested. The negative replicates tested at each time point were negative for all viral targets.

Table 20: Winter Excursion Results at 2X LoD

Virus	T=0 hrs 2X LoD		T=56 hrs 2X LoD			T=128 hrs 2X LoD		
	Pos/ Total	Mean Ct	Pos/ Total	Mean Ct	Delta Ct	Pos/ Total	Mean Ct	Delta Ct
Flu A	20/20	33.11	20/20	35.73	2.62	20/20	35.37	2.26
Flu B	20/20	33.33	20/20	35.46	2.13	20/20	35.90	2.57
RSV	20/20	34.37	**19/20**	36.57	2.20	**19/20**	36.72	2.35
SARS-CoV-2	20/20	30.55	20/20	31.23	0.68	20/20	31.33	0.78

Table 21: Winter Excursion Results at 10X LoD

Virus	T=0 hrs 10X LoD		T=56 hrs 10X LoD			T=128 hrs 10X LoD		
	Pos/ Total	Mean Ct	Pos/ Total	Mean Ct	Delta Ct	Pos/ Total	Mean Ct	Delta Ct
Flu A	10/10	30.82	10/10	32.90	2.08	10/10	32.83	2.01
Flu B	10/10	31.25	10/10	33.00	1.75	10/10	33.58	2.33
RSV	10/10	31.46	10/10	33.31	1.85	10/10	34.45	2.99
SARS-CoV-2	10/10	28.37	10/10	29.17	0.80	10/10	29.19	0.82

b) Summer Temperature Excursion:

To extend the summer shipping stability of SARS-CoV-2, Influenza A, Influenza B, and RSV specimens when using the Labcorp COVID-19+Flu+RSV Test Home Collection Kit, a specimen stability study was performed (Tables 22-24). After performance of the recommended 56-hour summer shipping excursion, specimens were stored for an additional 72 hours at room temperature.

Table 22: Summer Temperature Excursion

Cycle Period	Temperature	Cycle Time (Hours)	Total Time after T=0 (Hours)
1	40°C	8	8
2	22°C	4	12
3	40°C	2	14
4	30°C	36	50
5	40°C	6	56
6	Room Temperature	24	80*
7	Room Temperature	72	128

*RSV specimens were not tested at T=80 hours

Stability specimens were generated by separately spiking viral strains A/Nebraska/14/2018, B/Colorado/06/2017, and RSV B Washington as well as a SARS-CoV-2 remnant patient specimen into individual negative anterior nasal swab specimens (saline) to yield concentrations at 2X the LoD (3.12, 3.12, 12.50, and 3.12 cp/µL, respectively) or 10X the LoD (15.60, 15.60, 62.50, and 15.60 cp/µL, respectively). Twenty 2X LoD specimen replicates and ten 10X LoD specimen replicates of each viral type were subjected to the extended summer profile. Ten negative specimen replicates were also included to monitor specimen contamination.

Table 23: Summer Excursion Results at 2X LoD

Virus	T=0 hrs 2X LoD		T=56 hrs 2X LoD			T=80 hrs 2X LoD			T=128 hrs 2X LoD		
	Pos/ Total	**Mean Ct**	**Pos/ Total**	**Mean Ct**	**Delta Ct**	**Pos/ Total**	**Mean Ct**	**Delta Ct**	**Pos/ Total**	**Mean Ct**	**Delta Ct**
Flu A	20/20	31.26	20/20	33.22	1.96	20/20	32.94	1.68	20/20	33.63	2.37
Flu B	20/20	32.50	20/20	33.97	1.47	20/20	35.23	2.73	20/20	34.67	2.17
SARS-CoV-2	20/20	**32.12***	20/20	34.46	2.34	20/20	35.12	3.00	20/20	34.41	2.29
RSV	20/20	34.40	20/20	36.20	1.80	-	-	-	**19/20**	**36.11****	1.71

RSV specimens were not tested at T=80 hours
* when calculating the Ct mean, the outlier value of 28.56 was not included
** Failing specimen omitted from calculation

Table 24: Summer Excursion Results at 10X LoD

Virus	T=0 hrs 10X LoD		T=56 hrs 10X LoD			T=80 hrs 10X LoD			T=128 hrs 10X LoD		
	Pos/ Total	Mean Ct	Pos/ Total	Mean Ct	Delta Ct	Pos/ Total	Mean Ct	Delta Ct	Pos/ Total	Mean Ct	Delta Ct
Flu A	10/10	28.77	10/10	30.17	1.40	10/10	30.52	1.75	10/10	30.33	1.56
Flu B	1010	29.79	1010	31.20	1.41	1010	32.25	2.46	1010	31.74	1.95
SARS-CoV-2	10/10	29.03	10/10	32.02	2.99	10/10	32.93	**3.90**	10/10	31.89	2.86
RSV	10/10	30.80	10/10	33.24	2.44	-	-	-	10/10	32.48	1.68

RSV specimens were not tested at T=80 hrs

Flu A, Flu B, and SARS-CoV-2 replicates were tested at T=0, 56, 80, and 128 hours using the Labcorp Seasonal Respiratory Virus RT-PCR Test and remained positive at all time points. RSV replicates tested at 0, 56 and 128 hours all remained positive during the excursions except for one 2X LoD replicate at the T = 128-hour time point.

In all cases except one, the mean Ct values at T=56 hours, T=80 hours and T=128 hours for all four targets differed by no more than 3.0 Ct compared to T=0. At T=80 hours, the 10X SARS-CoV-2 replicates returned an average delta Ct of 3.90. Since all delta Ct values were not greater than 3 for the T=128-hour time point, this suggests the T=80-hour specimen processing (extraction/amplification) was sub-optimal during testing. Therefore, it was this sub-optimal processing that resulted in the greater average delta Ct values and not the loss of viral stability. The negative replicates tested at each time point were negative for all viral targets.

This data supports the stability of anterior nasal swab specimens collected with the Labcorp COVID-19+Flu+RSV Test Home Collection Kit for up to 56 hours in shipping environment during summer and winter followed by 72 hours at room temperature after laboratory receipt.

9) ***Carry-over/Cross-Contamination***

To demonstrate a lack of carry-over and cross-contamination for the Labcorp Seasonal Respiratory Virus RT-PCR Test, alternating high-positive specimens and negative specimens were assayed on six separate runs. Each run consisted of three replicates each of Flu A, Flu B, RSV A, RSV B, SARS-CoV-2 at 1 x 10^5 $TCID_{50}$/mL and twelve negatives alternating in a checkerboard configuration. Negatives consisted of pooled negative anterior nasal swab specimens (saline). All negative specimens were found negative for all viral targets, demonstrating no carry-over or cross-contamination during the assay procedure.

10) Precision

Within-lab precision of the Labcorp Seasonal Respiratory Virus RT-PCR Test was assessed by repeat testing a panel of specimens. Specimens included co-spiked strains A/Nebraska/14/2018, B/Colorado/06/2017, and SARS-CoV-2 USA-WA1/2020 at 1X LoD (1.56 cp/µL each) and 3X LoD (4.68 cp/µL each) as well as RSV B Washington alone at 1X LoD (6.25 cp/µL) and 3X LoD (18.75 cp/µL). Dilutions were generated using pooled negative anterior nasal swab specimens (saline). Negative replicate specimens were included in the panel to monitor contamination.

Each of the 5 specimen types was tested in quadruplicate for a total of 20 specimens per run. Two operators performed separate runs each day over six non-consecutive days. In addition, 2 different instrument sets and 2 different reagent lots were used. See Table 25 for a summary of the testing parameters.

Table 25: Precision Testing Parameters

Day	Run	Operator	Instrument	Lot	Specimens	Reps per conc.	Total specimens per run
1	1	1	1	1	1. 1X LoD – FLUA/B/ SARS-CoV-2 2. 3X LoD – FLUA/B/ SARS-CoV-2 3. 1X LoD – RSV 4. 3X LoD – RSV 5. Negative	4	20
	2	2	2	2		4	20
2	1	2	2	1		4	20
	2	1	1	2		4	20
3	1	1	2	2		4	20
	2	2	1	1		4	20
4	1	2	1	2		4	20
	2	1	2	1		4	20
5	1	1	2	2		4	20
	2	2	1	1		4	20
6	1	2	1	2		4	20
	2	1	2	1		4	20

The positivity rate was calculated for each target at each concentration using the results generated from all days. In addition, the overall mean Ct, standard deviation (SD), and % coefficient of variation (%CV) were calculated. All 3X LoD target replicates showed a 100% positivity rate and all 1X LoD target replicates showed a $\geq$ 95% positivity rate, except for RSV which had a positivity rate of 91.7% for the

1xLoD specimen. The negative specimens achieved 100% negative results for all assay targets. See Table 26 for the summarized results.

Table 26: Summary of Within-Laboratory Precision

Virus	Concentration	Pos/Total	Positivity Rate (95% CI)	Mean Ct	S.D.	%CV
Flu A	Negative	0 / 48	0.0% (0.0 – 7.4)	N/A**	N/A	N/A
	1X LOD	47 / 48	97.9% (89.1 – 99.6)	37.62*	1.19	3.15
	3X LOD	48 / 48	100.0% (92.6 – 100.0)	35.19	0.82	2.34
Flu B	Negative	0 / 48	0.0% (0.0 – 7.4)	N/A	N/A	N/A
	1X LOD	48 / 48	100.0% (92.6 – 100.0)	35.89	0.71	1.97
	3X LOD	48 / 48	100.0% (92.6 – 100.0)	34.05	0.43	1.27
RSV	Negative	0 / 48	0.0% (0.0 – 7.4)	N/A	N/A	N/A
	1X LOD	44 / 48	91.7% (80.5 – 96.7)	37.84*	2.25	5.95
	3X LOD	48 / 48	100.0% (92.6 – 100.0)	33.81	2.12	6.27
SARS-CoV-2	Negative	0 / 48	0.0% (0.0 – 7.4)	N/A	N/A	N/A
	1X LOD	48 / 48	100.0% (92.6 – 100.0)	36.45	0.70	1.93
	3X LOD	48 / 48	100.0% (92.6 – 100.0)	34.76	0.64	1.84

*replicates returning a negative result were assigned a Ct value of 40
**Not applicable

Additionally, ANOVA analysis was performed to quantify within runs, between days, between operators, between instruments, between reagent lots, and between runs precision. See Table 27 for a summary of the results.

Table 27: Summary of Precision Between Different Parameters

Virus	Conc.	Within Runs		Between Days		Between Operators		Between Instruments		Between Reagent Lots		Between Runs	
		SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Flu A	1X LOD	1.16	3.08	0.91	2.42	2.21	5.88	1.35	3.60	1.32	3.51	0.38	1.02
	3X LOD	0.83	2.35	1.06	3.00	3.26	9.26	2.59	7.36	0.22	0.63	0.78	2.22
Flu B	1X LOD	0.70	1.96	1.29	3.59	0.86	2.38	0.87	2.42	0.93	2.60	0.83	2.32
	3X LOD	0.41	1.20	0.52	1.54	1.37	4.01	0.87	2.57	0.19	0.56	1.08	3.17
RSV	1X LOD	2.05	5.43	1.55	4.09	2.52	6.66	3.06	8.09	2.67	7.07	2.66	7.03
	3X LOD	2.13	6.31	2.73	8.07	1.23	3.63	0.26	0.76	0.86	2.53	1.34	3.96
SARS-CoV-2	1X LOD	0.71	1.95	0.76	2.09	0.22	0.59	0.56	1.52	0.57	1.56	0.31	0.85
	3X LOD	0.65	1.86	1.18	3.39	0.36	1.05	1.38	3.96	0.23	0.65	0.06	0.17

11) Fresh vs. Frozen Test Specimens

A study was performed to determine the effect of specimen freezing on detectability. Specimens included 10 replicates of co-spiked strains A/Nebraska/14/2018, B/Colorado/06/2017, and SARS-CoV-2 USA-WA1/2020 at 1X LoD (1.56 cp/µL each) and 3X LoD (4.68 cp/µL each) as well as 10 replicates of RSV B Washington alone at 1X LoD (6.25 cp/µL) and at 3X LoD (18.75 cp/µL). Dilutions were generated using pooled negative anterior nasal swab specimens (saline). In addition, 10 negative replicates were included to monitor contamination. Specimens were tested immediately after generation and then after a freeze-thaw cycle. After freezing, all target replicates were still detectable and the mean Ct values for all targets were within 3.0 Ct, indicating minimal loss of sensitivity (Table 28). All negatives returned negative target results.

Table 28: Fresh Versus Frozen Specimen Results

Virus	Pre-Freeze 1X LoD		Post-Freeze 1X LoD			Pre-Freeze 3X LoD		Post-Freeze 3X LoD		
	Pos/ Total	Mean Ct	Pos/ Total	Mean Ct	Delta Ct	Pos/ Total	Mean Ct	Pos/ Total	Mean Ct	Delta Ct
Flu A	10/10	36.69	10/10	37.33	0.64	10/10	34.96	10/10	35.76	0.8
Flu B	10/10	35.33	10/10	37.24	1.91	10/10	33.89	10/10	35.40	1.51
RSV	10/10	34.44	10/10	36.94	2.5	10/10	33.30	10/10	35.44	2.14
SARS-CoV-2	10/10	36.85	10/10	35.89	-0.96	10/10	35.12	10/10	34.15	-0.97

12) Clinical Evaluation

Fifty Flu A-positive, 30 Flu B-positive, 30 RSV-positive, and 50 negative clinical specimens were tested using the Labcorp Seasonal Respiratory Virus RT-PCR Test and the FDA-cleared molecular test as a comparator. Clinical specimens consisted of nasopharyngeal swabs from symptomatic individuals collected in UTM that were all archived frozen in the previous four years. Collection dates are noted with the line data. The positive percent agreement (PPA) for Flu A, Flu B, and RSV were all 100%. The negative percent agreement (NPA) was 100%. See Table 29 for the summarized results.

Ninety-three SARS-CoV-2-positive and 44 negative nasopharyngeal swab archived clinical specimens in UTM were tested with the Labcorp Seasonal Respiratory Virus RT-PCR Test and also using a highly sensitive EUA-authorized molecular assay as a comparator. The comparator assay has a SARS-CoV-2 Ct value of approximately 35.9 at the LoD. At least 20% of the SARS-CoV-2 specimens were low positives (within a comparator Ct value range of 32.6 to 38.6). The PPA for SARS-CoV-2 was found to be 96.7% with a lower bound 95% confidence interval of 90.9%. The NPA was 100%. Three of the negative specimens had failing internal controls and were omitted from analysis. See Table 29 for the summarized results.

Table 29: Clinical Concordance Results for the Labcorp Seasonal Respiratory Virus RT-PCR Test

	FLU A, Flu B and RSV Specimens				SARS-CoV-2 Specimens	
Target >	**FluA**	**FluB**	**RSV**	**Negative**	**SARS-CoV-2**	**Negative**
Concordant	50	30	30	50	90	41
False Neg	0	0	0	0	3	0
False Pos	0	0	0	0	0	0
Failing RNase P	0	0	0	0	0	3
Total	50	30	30	50	93	44
PPA (95% CI)	100.0% (92.9-100)	100.0% (88.7-100)	100.0% (88.7-100)	N/A	96.7% (90.9-98.9)	N/A
NPA (95% CI)	NA	NA	NA	100.0% (92.9-100)	NA	100.0% (91.4-100)

As a condition of authorization, Labcorp will conduct a post-authorization prospective clinical study to evaluate performance of the Labcorp Seasonal Respiratory Virus RT-PCR test using self-collected anterior nasal swab specimens in the intended use population for all the claimed analytes.

13) Human Usability Study for the Labcorp COVID-19+Flu+RSV Test Home Collection Kit

The instructions for use of the Labcorp COVID-19+Flu+RSV Test Home Collection Kit are the same as those for the Labcorp At Home COVID-19 Test Home Collection Kit (EUA200011). Therefore, the study demonstrating usability of the Labcorp At Home COVID-19 Test Home Collection Kit is applicable to the usability of the Labcorp COVID-19+Flu+RSV Test Home Collection Kit.

The details of the usability study to support collection with the Labcorp At Home COVID-19 Test Home Collection Kit are available in Labcorp's COVID-19 RT-PCR Test (EUA200011) EUA summary: https://www.fda.gov/media/136151/download

LIMITATIONS:

- Nasopharyngeal (NP), mid-turbinate and anterior nasal specimens are considered acceptable specimen types for use with the Labcorp Seasonal Respiratory Virus RT-PCR Test. Testing of anterior nasal specimens is limited to individuals ages 18 years and older (self-collected), 14 years and older (self-collected with adult supervision), or 2 years and older (collected with adult assistance) when directly ordered by an HCP.
- A false negative result may occur if a specimen is improperly collected, transported or handled. False negative results may also occur if amplification inhibitors are present in the specimen or if inadequate numbers of organisms are present in the specimen.
- This test cannot rule out diseases caused by other bacterial or viral pathogens.
- Results from the Labcorp Seasonal Respiratory Virus RT-PCR Test should be used as an adjunct to clinical observations and other information available to the physician. The result is only for clinical

reference, and the clinical management of patients should be considered in combination with their symptoms/signs, history, other laboratory tests and treatment responses.

- Although the detected target sequences of this test are in conserved regions of the SARS-CoV-2, influenza A/B and RSV genomes, rare mutations may lead to negative results.
- Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for treatment or other patient management decisions. Optimum specimen types and timing for peak viral levels during infections caused by SARS-CoV-2 have not been determined.
- Results (positive and negative) for influenza and RSV should be interpreted with caution. If an influenza or RSV result is inconsistent with clinical presentation and/or other clinical and epidemiological information, FDA-cleared influenza and RSV NAATs are available for confirmation if clinically indicated.
- When using the Labcorp Seasonal Respiratory Virus RT-PCR Test, RSV demonstrated a drop in sensitivity when it was tested along with SARS-CoV-2, influenza A and influenza B co-spiked at their respective LoD.
- When using the Labcorp Seasonal Respiratory Virus RT-PCR Test, a high concentration of the Influenza B analyte may inhibit the detection of Influenza A and RSV.
- When using the Labcorp Seasonal Respiratory Virus RT-PCR Test, a high concentration of Afrin (>5% v/v) may inhibit detection of influenza A.The performance of this test was established based on the evaluation of a limited number of clinical specimens. Clinical performance has not been established with all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.
- Potential assay interference due to live influenza virus vaccine such as FluMist has not been evaluated.

WARNINGS:

- For in vitro diagnostic use under FDA Emergency Use Authorization only.
- For Prescription Use only.
- This product (collection kit in combination with the authorized test) has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.
- This product has been authorized only for the detection and differentiation of nucleic acid from SARS-CoV-2, influenza A, influenza B and/or Respiratory Syncytial Virus (RSV), not for any other viruses or pathogens.
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.